REMARKS

Preliminary Matter

Pursuant to a substitute Power of Attorney filed herewith, Applicant respectfully requests that the Attorney Docket number be changed to: **17257/005001**, and that future communications be directed to the address associated with PTO customer number: **22511**.

Disposition of the Claims

Claims 1-10 were pending. New claims 11-15 have been added by this reply. Therefore, claims 1-15 are currently pending. Claim 1, 6, and 12 are independent. Claims 2-5, 7-11, and 13-15 depend, directly or indirectly, from claim 1, 6, or 12.

Claim Amendments

Claims 1-10 have been amended to clarify the inventions recited. New claims 11-15 have been added. No new matter is introduced by these amendments as supports for these amendments can be found at least in the original claims or in paragraphs [0036] and [0041] of the U.S. Patent Application Publication No. 2006/0189521 A1.

Response to the Restriction Requirement

The Examiner asserts that the original claims include 9 inventions. These claims have been amended. To the extent that the restriction may still apply to the amended claims, the restriction is respectfully traversed for the following reasons.

Applicant respectfully notes that this application is a National Stage application, under 35 U.S.C. § 371, based on a PCT application. Therefore, the "unity of invention" concept under PCT rules 13.1 and 13.2 should be followed. *See*, 37 CFR § 1.475 and § 1.499 et seq. MPEP § 1850.

"Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. . . . If the

independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims." MPEP § 1850. Thus, it is improper for the Examiner to require restriction of the dependent claims.

Under PCT Rule 13.2, unity of invention exists when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims as interpreted in light of the description and drawings. "If . . . there is a single general inventive concept that appears novel and involves inventive step, then there is unity of invention and an objection of lack of unity does not arise. . . . the benefit of any doubt being given to the applicant." MPEP § 1850.

With respect to the instant invention, the "special technical feature" that contributes over the prior art is the discovery of hLRTM4 and its roles in liver regeneration (Example 8) and GI cancers (paragraph [0058] and Examples 4-7). Specifically, the inventors have found that hLRTM4 can prevent and treat liver injuries, while antagonists of hLRTM4 can be used to treat liver and stomach cancers.

Claims 1-5 are directed to compositions comprising hLRTM4 proteins or genes and their uses in treating liver injuries, and claims 6-11 are directed to compositions comprising antagonists of hLRTM4 proteins or gene products and their uses in treating liver or stomach cancers. New claims 12-15 are product claims directed to the hLRTM4 protein and polynucleotides encoding this protein.

Applicant respectfully submits that unity of invention exists because these claims share the common special technical features – hLRTM4 related products or compositions and the uses of these compositions in treating liver disorders or cancers.

Combination of Different Categories of Claims Are Permitted if Unity of Invention Exists

MPEP § 1850 provides: "In applying PCT Rule 13.2 . . . to national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2."

As illustrated in the Administrative Instructions, Annex B, the method for determining unity of invention under PCT Rule 13.2 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same application:

(i) in addition to an independent claim for a given product, an independent claim for a process specifically adapted for the manufacture of said product, and an independent claim for a use of said product. . . .

All amended claims are directed to products or compositions and the uses of these products or compositions. Therefore, Applicant respectfully submits that unity of invention exists among these claims.

The Markush Group in Claim 5

The situation involving the so-called "Markush practice" wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this specific situation, the requirement of a technical interrelationship and the same or corresponding special technical features, as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

The Examiner asserts that the disorders listed in claim 5 "have different etiologic considerations and are not considered obvious variants of each other." (Office Action, p. 4, lines 1-2). This approach is improper for the PCT "unity of invention" inquiry. The proper inquiry,

under PCT Rule 13.2, shall be whether these alternatives have the same or corresponding technical features that define a contribution over the prior art. Note that in this inquiry, each invention shall be considered as a whole.

A "special technical feature," which defines a contribution that each of the listed inventions (corresponding to the Markush alternatives), considered as a whole, makes over the prior art, is the use of an antagonist of hLTM4 to treat liver injury. The individual liver injuries listed in claim 5 are known liver injuries and do not constitute the "special technical features" that define the contribution over the prior art.

The criteria from Section (f)(i)(a) of Annex B of the PCT Administrative Instructions and used by the Examiner are for chemical compounds. The inquiry for chemical compounds is whether there is a common "structure" or "activity" to justify keeping them together. These "structure" or "activity" inquiries are irrelevant to the disorders listed in claim 5.

Therefore, Applicant respectfully submits that the restriction requirement among the various liver injuries is improper. Accordingly, withdrawal of this requirement is respectfully requested.

Conclusion

As noted above, the restrictions applied to the dependent claims and to the Markush group are improper. Furthermore, the Examiner seems to have used the criteria under 35 U.S.C. § 121, instead of PCT Rules 13.1 and 13.2, to arrive at 9 different groups of inventions. Since improper criteria had been used in the Restriction Requirement, Applicant respectfully requests that the Restriction Requirement be withdrawn.

For reasons set forth above, Applicant submits that all pending claims share a special technical feature that defines a contribution over the prior art – i.e., the uses of the hLRTM4 products in the treatments of disorders or cancers based on the functions of hLRTM4. In the event that the Examiner insists that Restriction is necessary, Applicant respectfully requests that a new action be issued.

In the event that the Examiner asserts that the last Restriction Requirement is proper, Applicant elects with traverse Group III, which includes the amended claims 6, 7, and 10 , which are directed to compositions comprising antisense polynucleotides. In this case, the amended claims 8 and 9, which are directed to the use of such compositions, should also be included, because under PCT Rule 13.2, unity of invention is clearly present between product/composition claims and the claims of using these products or compositions. (*see* the Administrative Instructions, Annex B).

Applicant believes this reply is fully responsive to all outstanding issues and places this application in condition for allowance. If this belief is incorrect, or other issues arise, the Examiner is encouraged to contact the undersigned or his associates at the telephone number listed below. Please apply any charges not covered, or any credits, to Deposit Account 50-0591 (Reference Number17257/005001).

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Respectfully submitted,

By _____

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